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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,014	10/28/2003	Constantin Polychronakos	MGU-0020	4261

7590

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EXAMINER
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MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/695,014	POLYCHRONAKOS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/22/03</u> . | 6) <input type="checkbox"/> Other: _____  |

### ***Claim Objections***

Claims 1 and 11 are objected to because of the following informalities:

on line 13 of claim 1, "unit for said" should be replaced with "unit for measuring";

on line 2 of claim 11, " $T_m$ " should be replaced with "a specific DNA sequence melting temperature  $T_m$ ". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 recites the limitation "a measuring unit for said impedance measurement evoked current" and "a means for comparing said impedance measurement evoked current with a predetermined value to obtain a comparison" on lines 11-16 of the claim. The applicants' specification fails to describe any means for comparing said impedance measurement evoked current with a predetermined value to obtain a comparison. It is noted that the specification details using a measured impedance to determine glucose level (see p. 6, lines 15-25) and discusses impedance measurements at length (p. 9, line 30-p. 13, line 2; p. 15, line 13-p. 14, line 3), but the specification fails to address *current* in a similar fashion. The specification further lacks an explanation of the phrase

Art Unit: 3736

"impedance measurement evoked current". Without referencing the specification, "impedance measurement evoked current" indicates that it is the current, rather than the impedance, being measured and compared. Therefore, it is additionally unclear, based on the discrepancy between the claim language and the specification, whether an impedance measurement or a current measurement is meant by the phrase. For the purposes of this application, the phrase is being interpreted as measuring and comparing a resulting current, as phrased in the claim language, rather than impedance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,497,772 to Schulman et al. Schulman discloses a glucose quantification device comprising a reference electrode REF1, a counter electrode CNTR, and a working electrode W1 (col. 6, lines 53-56; figs. 2A, 3, 4A, & 4B of Schulman) with a semipermeable membrane 55, 56, 96, 100 (col. 6, lines 60-67; col. 9, lines 3-14; figs. 2A & 4B of Schulman). During use, these electrodes are immersed in a liquid medium in which at least one chemical entity is dissolved (col. 5, lines 55-58; col. 6, lines 63-65 of Schulman). A potentiostat 60 applies a measurement potential to the working electrode relative to the reference electrode corresponding to a measurement

voltage during at least a portion of the measurement period (col. 6, line 58-col. 7, line 8; fig. 2A of Schulman), thereby causing the chemical entity to participate in an electrochemical reaction. The reaction results in an impedance measurement evoked current, which is measured by a measuring unit 75 (col. 7, lines 9-13; col. 7, lines 33-65 of Schulman). A monitor 34 compares the current with a predetermined value to obtain a comparison result (col. 8, lines 6-13; fig. 1 of Schulman).

Regarding claim 2, the liquid medium is blood (col. 6, lines 63-65 of Schulman).

Regarding claim 3, the chemical entity is glucose (col. 5, lines 56-59; col. 6, line 63-col. 7, line 8 of Schulman).

Regarding claim 7, the reference electrode is silver chloride (col. 7, lines 9-11 of Schulman).

Regarding claim 8, the counter electrode is platinum (col. 7, lines 8-9 of Schulman).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication 2004/0011671 to Shults et al. in view of US Patent No. 6,207,369 to Wohlstadter et al. Shults discloses a glucose quantification device comprising a reference electrode 20, a counter electrode 22, and a working

Art Unit: 3736

electrode 21 with a semipermeable membrane (paragraphs 0068, 0074, & 0079; fig. 1B of Shults). During use the sensor is immersed in a liquid medium in which at least one chemical entity is dissolved (lines 1-4 of paragraph 0070 of Shults). Shults discloses that the electronic circuit means used with this sensor may be that of US Patent No. 5,497,772 to Schulman et al., which is incorporated by reference into the Shults reference (paragraph 0019 of Shults). The electronic circuit means of Schulman includes a potentiostat 60 applies a measurement potential to the working electrode relative to the reference electrode corresponding to a measurement voltage during at least a portion of the measurement period (col. 6, line 58-col. 7, line 8; fig. 2A of Schulman), thereby causing the chemical entity to participate in an electrochemical reaction. The reaction results in an impedance measurement evoked current, which is measured by a measuring unit 75 (col. 7, lines 9-13; col. 7, lines 33-65 of Schulman). Shults teaches the working electrode comprising platinum (paragraph 0068 of Shults) rather than a semiconductor.

However, Wohlstadter describes a sensor that may be used to monitor glucose (col. 51, line 31) and which comprises a working electrode may be made of platinum or a semiconductor (col. 61, lines 31-36 of Wohlstadter). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a semiconductor material in place of platinum for the working electrode of Shults, since Wohlstadter teaches the two materials being functionally equivalent in a glucose sensor.

Regarding claim 2, the liquid medium is blood (paragraphs 0038 & 0070 of Shults).

Regarding claim 3, the chemical entity is glucose (paragraph 0038 of Shults).

Regarding claim 4, the working electrode is covered with immobilized Concanavalin A that binds glucose (paragraphs 0068, 0074 and claims 32-36 of Shults).

Regarding claim 5, the semipermeable membrane allows for free diffusion of micromolecules but prevents macromolecules from contacting the Concanavalin A surface (paragraph 0079 of Shults).

Regarding claim 7, the reference electrode is Ag/AgCl (paragraph 0068 of Shults).

Regarding claim 9, the counter electrode is platinum (paragraph 0068 of Shults).

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,569,186 to Lord et al. in view of Schulman. Lord discloses a method and system in which signals from an implantable glucose sensor 20 (col. 3, lines 54-65; col. 4, lines 10-22 of Lord) are used to control administration of insulin to modulate a patient's glucose levels via a feedback loop pump 10 (col. 3, lines 25-42 of Lord). Lord discloses that the glucose sensor 20 generally comprises an implantable enzyme electrode (col. 4, lines 10-11 of Lord), but fails to specify details as to the sensor.

However, Schulman discloses a glucose quantification device comprising a reference electrode REF1, a counter electrode CNTR, and a working electrode W1 (col. 6, lines 53-56; figs. 2A, 3, 4A, & 4B of Schulman) with a semipermeable membrane 55, 56, 96, 100 (col. 6, lines 60-67; col. 9, lines 3-14; figs. 2A & 4B of Schulman). During use, these electrodes are immersed in a liquid medium in which at least one chemical entity is dissolved (col. 5, lines 55-58; col. 6, lines 63-65 of Schulman). A potentiostat 60 applies a measurement potential to the working electrode relative to the reference

Art Unit: 3736

electrode corresponding to a measurement voltage during at least a portion of the measurement period (col. 6, line 58-col. 7, line 8; fig. 2A of Schulman), thereby causing the chemical entity to participate in an electrochemical reaction. The reaction results in an impedance measurement evoked current, which is measured by a measuring unit 75 (col. 7, lines 9-13; col. 7, lines 33-65 of Schulman). A monitor 34 compares the current with a predetermined value to obtain a comparison result (col. 8, lines 6-13; fig. 1 of Schulman). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the sensor of Schulman with the system of Lord, since Lord teaches using an implantable glucose sensor, and Schulman describes such a sensor.

With further regard to claim 10, the description of the apparatus of Schulman inherently discloses a method of using the apparatus. Additionally, the current is compared with a predetermined value to determine whether the chemical entity in the liquid medium is within a normal range (col. 15, line 65-col. 16, line 19 of Schulman).

***Allowable Subject Matter***

Claim 6 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Regarding claim 6, the prior art of record fails to teach or fairly suggest a



glucose quantification device comprising a working electrode, wherein the working electrode contains at least one surface with a thin layer of silicon oxide.

Regarding claim 11, the prior art of record fails to teach or fairly suggest a method of determining a specific DNA sequence melting temperature  $T_m$  of the patient by continuously determining the impedance measurement evoked current value over a period of time while increasing the temperature of the liquid medium.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,300,123 to Vagdama et al.

US Patent No. 6,110,696 to Brown et al.

US Patent No. 6,083,366 to Higson

US Patent No. 5,942,388 to Willner et al.

US Patent No. 4,436,094 to Cerami

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3736

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patricia Mallari  
Patent Examiner  
Art Unit 3736

  
ROBERT L. NASSER  
PRIMARY EXAMINER